Remarks

I. Support for Amendments

Support for the amendment to the claim 1 can be found on page 52, paragraph 0310 through page 53, paragraph 0313. Amendments to claims 61, 76-77, and 82-83 were made to correct minor dependency errors.

II. Status of the Claims

Reconsideration of this Application is respectfully requested.

By the foregoing amendment, claims 60 and 65-75 are cancelled without prejudice to or disclaimer of the subject matter therein, and claims 1, 61, 76-77, and 82-83 are sought to be amended. These amendments are made to place the claims in better form for allowance or consideration on appeal by materially reducing or simplifying the issues for appeal. These changes are believed to introduce no new matter, or raise new issues that would require further consideration and/or search. Entry of these amendments is respectfully requested.

Upon entry of the foregoing amendments, claims 1-10, 22-30, 43-59, 61, 76-88 and 138 are pending in the application, with claim 1 being the independent claim.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

III. The Rejection Under 35 U.S.C. § 112, First Paragraph

In section 7 of the Office Action at page 2, claims 1-10, 22-30, 43-62, 64-68, 73-88, and 138 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

The Office Action alleged that

> the claimed invention contains no identifying characteristics regarding the identified polynucleotide or the library of insert polynucleotides used. Additionally, the narrow scope of examples directed to the use of specific vaccinia virus vectors in tri-molecular-recombination method, which are clearly not representative of the scope of the presently claimed method.

Office Action at page 4. Applicants respectfully disagree and traverse this rejection as applied to the claims as amended.

Applicants respectfully point out that the test for written description requirement is whether one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02.

The Examiner contends that the specification "is directed to the use of specific Vaccinia virus vectors in trimolecular-recombination method, which clearly do not provide an adequate representation regarding the open ended claimed method for selecting a target polynucleotide of the instant claims." Office Action at page 3.

Applicants disagree with this statement, however, in an effort to facilitate prosecution, and not in acquiescence to the Examiner's rejection, Applicants have amended claim 1 to recite "wherein said library is constructed in a vaccinia virus vector

using trimolecular recombination and wherein expression of said target polynucleotide directly or indirectly promotes cell death."

The Examiner further contends that "the claimed invention contains no identifying characteristics regarding the identified polynucleotide or the library of insert polynucleotides used." Applicants respectfully submit that the Examiner's assertion that the specification must provide the identifying characteristics of "the polynucleotides identified using the claimed method." is erroneous. First, while it is true that the claimed method can be used to identifying previously known genes that may be involved directly or indirectly in host cell death, the present invention also allows "the use of vaccinia virus as a high efficiency cloning vector suitable for producing libraries." Thus, "vaccinia virus now may be used to identify previously unknown genes of interest from a complex population of clones, such as a cDNA or other library." In addition, "its ability to replicate in nondividing cells and its potential to express proteins at a high level in nondividing cells allows vaccinia virus to be used for cloning and isolating sequences that positively or negatively affect growth, differentiation, or cell viability." *See* specification at page 67. Therefore, contrary to the Examiner's assertion, the present invention is also directed toward selecting *previously unknown* target polynucleotides that are involved directly or indirectly in host cell death.

Furthermore, the Examiner's attention is directed to Example 18 of the USPTO's "Synopsis of Application of Written Description Guidelines" (available at http://www.uspto.gov/web/offices/pac/writtendesc.pdf). This Example illustrates an analysis of the written description provided for a process claim where the novelty is in the method steps. The claim at issue in this Example is as follows:

> A method of producing a protein of interest comprising;
>
> obtaining *Neurospora crassa* mitochondria,
>
> transforming said mitochondria with a expression vector comprising a nucleic acid that encodes said protein of interest,
>
> expressing said protein in said mitochondria, and recovering said protein of interest.

The claim is directed to the expression of any protein of interest, a virtually unlimited genus of proteins. Nonetheless, the Example concludes that the claimed invention is adequately described. According to the analysis provided in this Example:

> A review of the specification reveals that *Neurospora crassa* mitochondria gene expression is essential to the function/operation of the claimed invention. A particular nucleic acid is *not essential* to the claimed invention.
>
> A search of the prior art reveals that the claimed method of expression in *Neurospora crassa* is novel and unobvious.

Significantly, in assessing the written description of this hypothetical claim, the USPTO's Example does not even question whether the specification provides adequate description of the entire genus of "protein of interest" because the "protein of interest" is not itself being claimed. Thus, the analysis focuses on whether the process is adequately

described, not whether the individual elements identified in the practice of the process (*e.g.*, the different types of proteins of interest) are adequately described.

Analogously, the polynucleotides in the present claims are not themselves being claimed; they are simply elements identified in the practice of the claimed methods. Thus, the written description analysis should focus on whether or not the methods are adequately described (they are), not whether the polynucleotides are adequately described.

The Examiner's application of the written description requirement in the present case appears to assume that the polynucleotides that are being directly claimed; however, this is not the case. The polynucleotides are not being directly claimed. Nevertheless, the specification discloses numerous species of potential target polynucleotides including tumor suppressive genes, apoptosis-inducing genes, cell proliferation genes, genes that arrest cell cycle, essential genes, oncogenes, and genes that induce expression of a suicide gene construct that could be identified by the claimed method. *See* specification at paragraphs [0408]-[0423] (pp. 84-89), [0464]-[0485] (pp. 101-108), [0510]-[510] (pp. 116-117), and [0516]-[0538] (pp. 119-127).

Finally, the Examiner states that "the instant specification has not disclosed . . . the working examples in which the claimed method is used to identify the polynucleotides." *See* Office Action at page 7. Applicants note that a requirement of "working examples" is an incorrect application of the law with respect to the written description requirement. The written description requirement is met if the specification discloses relevant identifying characteristics sufficient to describe the claimed invention in such terms that a skilled artisan would recognize that the applicant was in possession

of the claimed invention. *See* M.P.E.P. § 2163(II)(A). Based on the comments above, Applicants respectfully assert that the disclosure adequately describes the claimed method.

Accordingly, in view of the USPTO's own guidelines on this topic, it must be concluded that the written description requirement of § 112, first paragraph, is fully satisfied for the currently presented claims. Thus, Applicants respectfully request that this rejection be reconsidered and withdrawn.

IV. Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Eric K. Steffe
Attorney for Applicants
Registration No. 36,688

Date: 10/12/05

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

441437